Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Mechanical Cough Assist Device on Respiratory and Hemodynamic Parameters in Patients With Respiratory Disorder After Heart Surgery

Protocol summary

Study aim
the effect of mechanical cough aid on respiratory parameters and Hemodynamics of patients with respiratory disorders after open heart surgery

Design
randomized controlled clinical trial..84 patients with open heart surgery regular randomly Block size six, Two groups: (intervention) and control

Settings and conduct
Adult ICU of Shahid Rajaei Cardiovascular Hospital, after receiving routine of respiratory physiotherapy . intervention once in the morning after surgery and once on the third day. Respiratory and hemodynamic indices measured, 2 hours ago, 2,8, 14, 24 hours after study the second day ,2 hours after the second n on The third days, Chest x-ray before, after 24 hours later , the amount of exhaled air (PFM) before, 2 hours after the first intervention, and 2 hours after the second intervention.

Participants/Inclusion and exclusion criteria
respiratory distress, first minute expiratory volume less than 80%, age 30-85 years, body mass index less than 35, cardiopulmonary pump less than 160 minutes, left ventricular ejection fraction more than 25%, non-dialysis, no history of tumor in Chest and thoracic surgery. Do not admit patients for whom any additional intervention is prohibited by the doctor and who suspected to be Quid-19.

Intervention groups
Cough aid is performed in the morning after surgery, once on the second day and once on the third day.

Main outcome variables
Respiratory indicators (BLOOD GAS)، Hemodynamic parameters (systolic blood pressure, diastolic blood pressure, respiratory rate and number Heart rate) and the presence or absence of atelectasis and is measurement PFM.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201105049280N1**
Registration date: **2022-01-18, 1400/10/28**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-18, 1400/10/28**
Update count: **0**

Registration date
2022-01-18, 1400/10/28

Registrant information

Name
Tahereh Abolghasemi

Name of organization / entity
Center of academic investigative cardio vascular of Shaid Rajaie

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-05, 1400/10/15

Expected recruitment end date
2022-02-20, 1400/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Mechanical Cough Assist Device on Respiratory and Hemodynamic Parameters in Patients With Respiratory Disorder After Heart Surgery

Public title
The Effect of Mechanical Cough Assist Device on Respiratory and Hemodynamic Parameters in Patients With Respiratory Disorder After Heart Surgery

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
All patients recovered after heart surgery • Patients with respiratory disorder, PFT<80 Patients aged 30-85 years Patients with morbid obesity (body mass index 35 and less than 35 kg / m2) Patients with a cardiopulmonary pump duration of 160 minutes or less Patients with left ventricular ejection fraction greater than 25% • Non-dialysis patients Patients without a history of thoracic and thoracic surgery

Exclusion criteria:
Patients with Quid-19 diagnosis Patients for whom any additional intervention is prohibited by the doctor's order.

Age
From **30 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
The study is a randomized controlled clinical trial.84 patients with open heart surgery Who are eligible for inclusion in the study And randomly blockis size Six . They are divided into two groups (intervention) and control through a computer CREATE A PANDOMISATION LIST that has an equal number of each group in each block. Like this(ABABBA ,ABABBA ,ABBABA, ...)

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
https://ethics.research.ac.ir/PortalCommittee.

Street address
Tehran, District 3, Tehran, Valiasr St., at the beginning of Niayesh Highway, Ayatollah Hashemi Rafsanjani Highway,

City
Tehran

Province
Tehran

Postal code
1995614331

Approval date
2021-10-02, 1400/07/10

Ethics committee reference number
IR.RHC.REC.1400.072

Health conditions studied

1

Description of health condition studied
Ooen heart surgery,Coronary by pass graft

ICD-10 code
I25.710

ICD-10 code description
Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina pectoris

Primary outcomes

1

Description
Respiratory indicators (blood gases), (PH,SPO، ,PO,PCO,HCO,BE)

Timepoint
Before intervention, 2 hours, 8 hours, 14 hours and 24 hours after the first intervention and 2 hours after the second intervention.

Method of measurement
The measurement was performed using a techno-media device.

2

Description
Hemodynamic parameters (systolic blood pressure, diastolic blood pressure, respiration rate and heart rate)

Timepoint
Before intervention, 2 hours, 8 hours, 14 hours and 24 hours after the

Method of measurement
Measurements were performed using a cardiac monitoring device.

3

Description
Presence or absence of atelectasis
Timepoint
قبل و 2ساعت بعد از مداخله اول ونوبت دوم بعد از مداخله دوم
Method of measurement
Observention chet X-Ray

Secondary outcomes

empty

Intervention groups

1

Description
In Intervention group: after extubated inThe first day after of receiving routine daily physiotherapy ,used mini Pegaso cough with made in the country Italy with 2 mode percosure and automatic . They receivele through a face mask 3-5 times of the first day and repeted 3 times of the second days. hemodynamic symptoms and blood gases before and 2,8,14,24 hours after the intervention of the first day and 2 hours After the second days intervention, it is measured in both groups. peack flow meterhow (measure air flows from lungs) before the intervention and 2 hours after the intervention, the first and second days are measured for 2 groups. Presence or absence of atelectasis Checked before intervention and 2hours after intervention by chest xray.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaei Cardiovascular Research Training Centerمحسن
Full name of responsible person
Mohsn Ziyfard
Street address
Tehran, District 3, Tehran, Valiasr St., at the beginning of Niayesh Highway, Ayatollah Hashemi Rafsanjani Highway,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohsen Ziyaefard
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Rajaie Cardiovascular, Medical and Research Center
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohsen Ziyaefard
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available